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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,260	03/26/2004	Gordon Nelson Arbuthnot	X10443F	1633
25885	7590	09/09/2004	EXAMINER	
ELI LILLY AND COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/811,260	ARBUTHNOT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Celia Chang	1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 25 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) 32-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 32-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. This application is a continuation of SN 10/235,617. Claims 1-31 have been canceled. Claims 32-39 are pending.

2. Claims 32-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Please note that if the claims are drawn to general process of size reduction for which applicants have pointed out that page 5 line 32 through page 6 line 5 and page 40 line 23 through page 41 line 10 were alleging to be supportive, then, the process encompassed the well known size reduction procedures of “hammer, pin or fluid energy mill”, thus, a 103 rejection is applicable and will follow.

If the claims are drawn to “specific” process of making a particular size range having “a mean particle size of less than about 25 microns and at least about 90% of said particles having size of less than about 50 microns”, then, such specific process lacks antecedent basis, description and enabling disclosure, thus, is considered NEW MATTER. Please note that the claims being drawn to the “comminuting” process does not achieve the particular size range since the term “comminuting” is “*to change into a powder: pulverize*” (see Webster dictionary). A process changing substance into powder does not innately contain any connotation that the powder has any particular size range/distribution. Especially, it is well known in the art that pulverization produces broad range of sizes and any limitation of a particular size range is achieved by “sieving” for which no descriptive support can be found in the specification.

3. Claims 32-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter, which were not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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If the claims are drawn to the art recognized process of “sieving” as size range selection, then a 103 rejection is proper and will follow. If the claims are intended for particular steps in achieving the specific having “a mean particle size of less than about 25 microns and at least about 90% of said particles having size of less than about 50 microns”, then, no enablement can be found for such step.

Please note that on page 40-41, while size range were checked or measured using US 4,605,517 (which disclosed that milling does not give favorable uniform size, col. 1 lines 48-51), no specific measure was disclosed as to how such size was maintained except by repeatedly passing through the milling device.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 32-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over specification pages 5-6, 40-41 in view of CA88:126272.

As it was admitted and disclosed on pages 5-6, 40-41 of the specification, the comminuting of the compound into smaller size having “a mean particle size of less than about 25 microns and at least about 90% of said particles having size of less than about 50 microns” is employing proper equipment with proper setting for operation, i.e. routine manufacturing

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processing at the time the invention was made (p. 6 spec, line 4-5). CA 88 evidenced that such equipment are equipped with size siever so that the equipment mechanically achieves the claimed size range.


The claims are, thus, as disclosed, the operation of manufacturing equipment at applicants' facility. There is nothing unobvious in carrying out routine manufacturing activity to obtain a desirable product size. Any unexpected results of the particular size of the product does not offer any unexpectancy for the processing since it was clearly disclosed that getting such size was routine repetition of size reduction to obtain the desirable range.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Sept. 3, 2004

  
Celia Chang  
Primary Examiner  
Art Unit 1625